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CASE RG/G-32603A



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Express Mail Label Number

10/2/06

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT 6,962,924 OF

RAY ET AL.

ISSUED: NOVEMBER 8, 2005

APPLICATION NO: 10/621,670

FILED: JULY 17, 2003

FOR: NOVEL SALT AND POLYMORPHS OF DESLORATADINE
HEMIFUMARATECertificate
OCT 06 2006
of CorrectionAttn.: Certificate of Correction OfficeCommissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450REQUEST FOR CERTIFICATE OF CORRECTION

Sir:

Pursuant to 37 CFR 1.322, it is hereby respectfully requested that a Certificate of Correction be issued for United States Patent 6,962,924 containing the corrections set forth on the appended Form PTO 1050.

Upon review of the patent mentioned above, applicants noted that some of the wrong claims were inserted in the patent. Claims 1-6 were canceled and new claims 7-21 were added in the Amendment which accompanied the RCE, dated May 21, 2004 (a copy is enclosed herewith). A further Amendment was filed on December 6, 2004 canceling claims 7, 10 and 13 (a copy is enclosed herewith). A still further Amendment was filed on March 28, 2005 canceling claims 14-15 (a copy is enclosed herewith). Claims 18 and 21 were cancelled in an Examiner's Amendment as noted in the Notice of Allowability which accompanied the Notice of Allowance, dated May 20, 2005 (a copy is enclosed herewith), leaving claims 8, 9, 11, 12, 16, 17, 19 & 20 as the allowed claims. These allowed claims should be replaced by the claims listed in the patent and have been renumbered claims 1-8 on the enclosed Certificate of

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Correction Forms PTO 1050. The above-mentioned Amendments and Examiner's Amendment all show the support needed to correct the patent.

Upon further review of the patent, Patentees noted that the first paragraph of the patent under the title needs to be corrected. The word "benefit" was misspelled, a comma is missing after the provisional application number and the word "file on" should be inserted before the filing date.

Also errors which appeared on patent are believed to be attributable to patentees and are evident from the table below:

<u>Location and/or Error in Printed Patent</u>	<u>Location of Support of these errors</u>
Column 6, line 3 of claim 8, delete "by"	Error made on line 2 of claim 8 on page 2 of Amendment, filed on May 21, 2004 (now renumbered as claim 1).
Column 6, line 3 of claim 9, delete "by"	Error made on line 2 of claim 9 on page 2 of Amendment, filed on May 21, 2004 (now renumbered as claim 2).
Column 7, line 3 of claim 11, replacement of "Claim 9" with "Claim 8"	Claim 11 line 2 on page 4 of Amendment, filed on May 21, 2004 (now renumbered as claim 3).
Column 7, line 3 of claim 16, insertion of "according to claim 8" before "comprising:"	Insertion was made in claim 16, line 2, page 5 of Amendment, filed on December 6, 2004 (now renumbered as claim 5).
Column 7, line 3 of claim 17, insertion of "according to claim 8" before "comprising:"	Insertion was made in claim 17, line 2, page 5 of Amendment, filed on December 6, 2004 (now renumbered as claim 6).
Column 7, lines 4 of claim 17, insertion of the word "anhydrons" before "ethanol"	Insertion of the word that was added in the Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 17 now renumbered claim 6).
Column 7, line 5 of claim 17, replacement of "desloratidine" with "desloratadine"	Misspelling of word in claim 17 on page 5 of Amendment, filed on May 21, 2004 (now renumbered as claim 6).
Column 8, line 1, insertion of the word "anhydrons" before "ethanol"	Insertion of the word that was added in the Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005.

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Column 8, line 2, continuation of claim 17, replacement of "desloratidine" with "desloratadine"	Misspelling of word in claim 17 on page 5 of Amendment, filed on May 21, 2004 (now renumbered as claim 6).
Column 8, line 4, continuation of claim 17, insertion of "and stirring for 30-45 minutes at this temperature;" before "to form a solid;"	Page 2 of Examiner's Amendment which accompanied the Notice of Allowability, date May 20, 2005 (claim 17 now renumbered as claim 6).
Column 8, line 5, continuation of claim 17, insertion of phrase "at this temperature" after the word "solid"	Page 2 of Examiner's Amendment which accompanied the Notice of Allowability, date May 20, 2005 (claim 17 now renumbered as claim 6).
Column 8, line 3 of claim 19, insertion of "according to claim 2" before "comprising:"	Insertion was made in claim 19, line 2 on page 5 of the Amendment dated, December 6, 2004 (now renumbered as claim 7).
Column 8, line 4 of claim 19, replace "mixing desloratidine, fumaric acid, and ethanol" with "mixing an ethanolic solution of desloratidine and fumaric acid"	Page 2 of Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 19 now renumbered claim 7).
Column 8, lines 5 and 6 of claim 19, insertion of "stirring for 30-45 minutes after mixing" before "to form a solid;"	Page 2 of Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 19 now renumbered claim 7).
Column 8, line 7 of claim 19, removal of the opened quote before "filtering"	Correcting clerical error (claim 19 now renumbered claim 7).
Column 8, line 7 of claim 19, insertion of the phrase "at this temperature" after the word "solid"	Page 2 of Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 19 now renumbered claim 7).
Column 8, line 3 of claim 20, insertion of "accordingly to Claim 2" before comprising:"	Insertion was made in claim 20, line 2, page 5 of Amendment, filed on December 6, 2004 (now renumbered as claim 8).
	Misspelling of word in claim 20 on line 3 of

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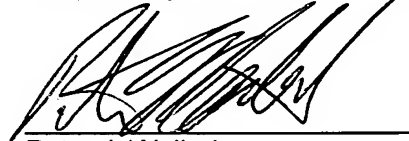
Column 8, line 5 of claim 20, replacement of "desloratidine" with "desloratadine"	Amendment, filed May 21, 2004 (now renumbered as claim 8).
Column 8, line 4, claim 20, removal of apostrophe before "dissolving"	Correcting clerical error (claim 20 now renumbered as claim 8).
Column 8, line 4, claim 20, insertion of "anhydrous" before "ethanol"	Page 3 of Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 20 now renumbered as claim 8).
Column 8, line 5 of claim 20, replacement of "desloratidine" with "desloratadine"	Misspelling of word in claim 20 on page 6 of Amendment, filed on May 21, 2004 (claim 20 now renumbered as claim 8).
Column 8, line 6, claim 20, removal of apostrophe before "dissolving"	Correcting clerical error (claim 20 now renumbered as claim 8).
Column 8, line 6, claim 20, insertion of "anhydrous" before "ethanol"	Page 3 of Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 20 now renumbered as claim 8)
Column 8, line 8 of claim 20, replacement of "desloratidine" with "desloratadine"	Misspelling of word in claim 20 on line 5 of Amendment, filed May 21, 2004 (now renumbered as claim 8).
Column 8, line 8, of claim 20, removal of apostrophe before "mixing"	Correcting clerical error (claim 20 now renumbered as claim 8)..
Column 8, line 10 of claim 20, insertion of "and stirring for 30-45 minutes after mixing before "to form a solid"	Insertion of words that were added in the Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 20 now renumbered claim 8).
Column 8, line 11 of claim 20, removal of the apostrophe before "filtering"	Correcting clerical error (claim 20 now renumbered as claim 8).
Column 8, line 11 of claim 20, insertion of "at this temperature" after "solid"	Insertion of words that were added in the Examiner's Amendment which accompanied the Notice of Allowability, dated May 20, 2005 (claim 20 now renumbered claim 8).

Attached is a duplicate of Form TO 1050, with at least one copy being suitable for printing.

Since some of the above errors are ascribable to the patentees, a fee is believed to be necessitated by this Request for Certification of Correction. The Commissioner is hereby authorized to charge any fee necessary to Deposit Account No. 19-0134 in the name of Novartis.

Please send the Certificate of Correction to the address currently associated with Customer No. 001095.

Respectfully submitted,



Peter J. Waibel
Attorney for Applicants
Reg. No. 43,228

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(862)778-7951

Encls.: copy of Amendment, dated May 21, 2004
copy of Amendment, dated December 6, 2004
copy of Amendment, dated March 28, 2005
copy of Notice of Allowability, dated May 20, 2005
PTO for 1050 (2)
post card

Date: 10/2/06

OCT 11 2006

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 6,962,924
DATED: : November 8, 2005
INVENTOR(S) : RAY ET AL.

It is certified that there is/are an error(s) in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, lines 4 and 5 should read:

-- This application claims the benefit of provisional application Ser. No. 60.401,153, filed on Aug. 5, 2002. --.

The allowed claims (8, 9, 11, 12, 16, 17, 19 and 20) have been renumbered as follows:

1. A Polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I₀"):

D	I/I ₀
12.32	26
10.53	11
8.444	19
8.149	16
6.550	25
6.281	22
6.185	35
6.084	19
5.553	88
5.373	64
5.096	59
4.960	41
4.745	34
4.470	26

MAILING ADDRESS OF SENDER:

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PATENT NO. 6,962,924

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4.745	34
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4.403	30
4.365	46
4.159	84
4.124	73
4.061	35
3.750	79
3.716	100
3.659	27
3.589	14
3.398	11
3.362	16
3.277	10
3.090	23
3.051	11
3.003	15
2.784	10
2.507	12

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PATENT NO. 6,962,924

FORM PTO-1050

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 6,962,924
DATED: : November 8, 2005
INVENTOR(S) : RAY ET AL.

2. A Polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity (" I/I_0 "):

D	I/I_0
14.14	14
10.74	13
7.158	39
7.084	20
5.983	12
5.663	61
5.365	33
5.267	100
5.064	12
4.973	46
4.809	16
4.745	43
4.477	32
4.449	26
4.399	60
4.317	54
4.012	49

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PATENT NO. 6,962,924

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3.772	26
3.745	61
3.722	97
3.590	88
3.561	59
3.385	24
2.986	17
2.949	11
2.836	20
2.778	10
2.616	10
2.481	12

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3. A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 1 according to Claim 1 and a pharmaceutically acceptable carrier.
4. A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 according to Claim 2 and a pharmaceutically acceptable carrier.
5. A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 1 comprising:
- (i) mixing an ethanolic solution of desloratadine and fumaric acid at a temperature of from about 15°C to about 25°C and stirring for 30-45 minutes at this temperature to form a solid; and
 - (ii) filtering the solid at this temperature to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 224°C ± 2°C.

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6. A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 1 comprising:

- (a) dissolving desloratadine in anhydrous ethanol to form an ethanolic solution of desloratadine;
- (b) dissolving fumaric acid in anhydrous ethanol to form an ethanolic solution of fumaric acid;
- (c) mixing the ethanolic solution of desloratadine and the ethanolic solution of fumaric acid at a temperature of from about 15°C to about 25°C and stirring for 30-45 minutes at this temperature to form a solid; and
- (d) filtering the solid at this temperature to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 224°C ± 2°C.

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7. A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 2 comprising:

- (i) mixing an ethanolic solution of desloratadine and fumaric acid at a temperature of from about 55°C to about 70°C and stirring for 30-45 minutes after mixing to form a solid; and
- (ii) filtering the solid at this temperature to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C \pm 2°C.

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8. A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 2 comprising:

- (a) dissolving desloratadine in anhydrous ethanol to form an ethanolic solution of desloratadine;
- (b) dissolving fumaric acid in anhydrous ethanol to form an ethanolic solution of fumaric acid;
- (c) mixing the ethanolic solution of desloratadine and the ethanolic solution of fumaric acid at a temperature of from about 55°C to about 70°C and stirring for 30-45 minutes after mixing to form a solid; and
- (d) filtering the solid at this temperature to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C ± 2°C.

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11/11/05

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2. A Polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I₀"):

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4. A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 according to Claim 2 and a pharmaceutically acceptable carrier.

5. A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 1 comprising:

(i) mixing an ethanolic solution of desloratadine and fumaric acid at a temperature of from about 15°C to about 25°C and stirring for 30-45 minutes at this temperature to form a solid; and

(ii) filtering the solid at this temperature to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 224°C ± 2°C.

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- (b) dissolving fumaric acid in anhydrous ethanol to form an ethanolic solution of fumaric acid;
- (c) mixing the ethanolic solution of desloratadine and the ethanolic solution of fumaric acid at a temperature of from about 15°C to about 25°C and stirring for 30-45 minutes at this temperature to form a solid; and
- (d) filtering the solid at this temperature to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 224°C ± 2°C.

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7. A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 2 comprising:

- (i) mixing an ethanolic solution of desloratadine and fumaric acid at a temperature of from about 55°C to about 70°C and stirring for 30-45 minutes after mixing to form a solid; and
- (ii) filtering the solid at this temperature to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C ± 2°C.

MAILING ADDRESS OF SENDER:

Peter J. Waibel
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PATENT NO. 6,962,924

FORM PTO-1050

OCT 11 2005

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 6,962,924
DATED: : November 8, 2005
INVENTOR(S) : RAY ET AL.

8. A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 2 comprising:

(a) dissolving desloratadine in anhydrous ethanol to form an ethanolic solution of desloratadine;

(b) dissolving fumaric acid in anhydrous ethanol to form an ethanolic solution of fumaric acid;

(c) mixing the ethanolic solution of desloratadine and the ethanolic solution of fumaric acid at a temperature of from about 55°C to about 70°C and stirring for 30-45 minutes after mixing to form a solid; and

(d) filtering the solid at this temperature to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C ± 2°C.

MAILING ADDRESS OF SENDER:

Peter J. Waibel

Novartis

Corporate Intellectual Property

One Health Plaza, Building 104

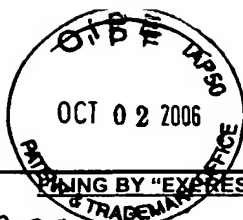
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PATENT NO. 6,962,924

FORM PTO-1050

OCT 11 2006



CASE RG/G-32603A

MAILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

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May 21, 2004
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
RAY ET AL.

Art Unit: 1625

Examiner: Evelyn Huang

APPLICATION NO: 10/621,670

FILED: JULY 17, 2003

FOR: NOVEL SALT AND POLYMORPHS OF DESLORATADINE
HEMIFUMARATE

MS: Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

(A)

AMENDMENT

Sir:

Prior to calculating the filing fee, kindly enter the following amendment.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

Claims 1-6 (canceled).

7. (new) A 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate.

8. (new) A polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having by the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity (" I/I_0 "):

d	I/I ₀
12.32	26
10.53	11
8.444	19
8.149	16
6.550	25
6.281	22
6.185	35
6.084	19
5.553	88
5.373	64
5.096	59
4.960	41
4.745	34
4.470	26
4.403	30
4.365	46
4.159	84
4.124	73
4.061	35
3.750	79
3.716	100
3.659	27
3.589	14
3.398	11
3.362	16
3.277	10
3.090	23
3.051	11
3.003	15
2.784	10
2.507	12

9. (new) A polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having by the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I₀"):

D	I/I ₀
14.14	14
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4.745	43
4.477	32
4.449	26
4.399	60
4.317	54
4.012	49
3.772	26
3.745	61
3.722	97
3.590	88
3.561	59
3.385	24
2.986	17
2.949	11
2.836	20
2.778	10
2.616	10
2.481	12

10. (new) A solid pharmaceutical composition comprising an anti-allergic effective amount of the compound of Claim 1 and a pharmaceutically acceptable carrier.

11. (new) A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 1 according to Claim 8 and a pharmaceutically acceptable carrier.

12. (new) A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 according to Claim 9 and a pharmaceutically acceptable carrier.

13. (new) A method of treating allergic reactions in a mammal which comprises administering to said mammal an anti-allergic effective amount of the compound of Claim 1.

14. (new) A method of treating allergic reactions in a mammal which comprises administering to said mammal an anti-allergic effective amount of the polymorph form 1 according to Claim 8.

15. (new) A method of treating allergic reactions in a mammal which comprises administering to said mammal an anti-allergic effective amount of the polymorph form 2 according to Claim 9.

16. (new) A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate comprising:

(i) mixing desloratadine, fumaric acid, and ethanol at a temperature of from about 15°C to about 25°C to form a solid; and

(ii) filtering the solid to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

17. (new) A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate comprising:

(a) dissolving desloratadine in ethanol to form an ethanolic solution of desloratidine;

(b) dissolving fumaric acid in ethanol to form an ethanolic solution of fumaric acid;

(c) mixing the ethanolic solution of desloratidine and the ethanolic solution of fumaric acid at a temperature of from about 15°C to about 25°C to form a solid; and

(d) filtering the solid to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

18. (new) The process according to Claim 17 wherein the mixing in Step (c) is conducted for a period of time from about 30 to about 45 minutes.

19. (new) A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate comprising:

(i) mixing desloratadine, fumaric acid, and ethanol at a temperature of from about 55°C to about 70°C to form a solid; and

(ii)" filtering the solid to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $232^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

20. (new) A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate comprising:

(a)' dissolving desloratadine in ethanol to form an ethanolic solution of desloratidine;

(b)' dissolving fumaric acid in ethanol to form an ethanolic solution of fumaric acid;

(c)' mixing the ethanolic solution of desloratidine and the ethanolic solution of fumaric acid at a temperature of from about 55°C to about 70°C to form a solid; and

(d)' filtering the solid to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $232^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

21. (new) The process according to Claim 20 wherein the mixing in Step (c)' is conducted for a period of time from about 30 to about 45 minutes.

Remarks

By the present amendment, applicants have canceled Claims 1-6, and added new Claims 7-21 in order to more clearly identify the invention. Support for new Claim 7 is found in the specification on page 1, lines 35. Support for new Claims 8 and 9 is found in canceled Claim 1. Support for new Claims 10-12 is found in canceled Claims 2-3. Support for new Claims 13-15 is found in canceled Claim 5. Support for new Claims 16-18 is found in canceled Claim 6, and in the specification on page 7, lines 17-27. Support for new Claims 19-21 is found in canceled Claim 6, and in the specification on page 7, lines 28-31, and in the specification on page 8, lines 1-6.

Applicants respectfully request the Examiner to enter the Amendment.

Respectfully submitted,

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Attorney for Applicants
Reg. No. 34,940

Date: May 21, 2004



CASE RG/G-32603A

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1625

RAY ET AL.

Examiner: Evelyn Huang

APPLICATION NO: 10/621,670

FILED: JULY 17, 2003

FOR: NOVEL SALT AND POLYMORPHS OF DESLORATADINE
HEMIFUMARATE

MS: Amendment

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

AMENDMENT

Sir:

The following amendment is in response to an Office Action dated July 6, 2004. A two month extension of time petition is included herewith.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

Claims 1-7 (cancelled).

8. (previously presented): A polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having by the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I₀"):

d	I/I₀
12.32	26
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4.745	34
4.470	26
4.403	30
4.365	46
4.159	84
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4.061	35
3.750	79
3.716	100
3.659	27
3.589	14
3.398	11
3.362	16
3.277	10
3.090	23
3.051	11
3.003	15
2.784	10
2.507	12

9. (previously presented): A polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having by the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I₀"):

D	I/I ₀
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3.561	59
3.385	24
2.986	17
2.949	11
2.836	20
2.778	10
2.616	10
2.481	12

10. (cancelled).

11. (previously presented): A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 1 according to Claim 8 and a pharmaceutically acceptable carrier.

12. (previously presented): A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 according to Claim 9 and a pharmaceutically acceptable carrier.

13. (cancelled).
14. (previously presented): A method of treating allergic reactions in a mammal which comprises administering to said mammal an anti-allergic effective amount of the polymorph form 1 according to Claim 8.
15. (previously presented): A method of treating allergic reactions in a mammal which comprises administering to said mammal an anti-allergic effective amount of the polymorph form 2 according to Claim 9.
16. (currently amended): A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 8 comprising:
- (i) mixing desloratadine, fumaric acid, and ethanol at a temperature of from about 15°C to about 25°C to form a solid; and
 - (ii) filtering the solid to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
17. (currently amended): A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 8 comprising:
- (a) dissolving desloratadine in ethanol to form an ethanolic solution of desloratidine;
 - (b) dissolving fumaric acid in ethanol to form an ethanolic solution of fumaric acid;
 - (c) mixing the ethanolic solution of desloratidine and the ethanolic solution of fumaric acid at a temperature of from about 15°C to about 25°C to form a solid; and
 - (d) filtering the solid to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
18. (previously presented): The process according to Claim 17 wherein the mixing in Step (c) is conducted for a period of time from about 30 to about 45 minutes.
19. (currently amended): A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 9 comprising:

(i)' mixing desloratadine, fumaric acid, and ethanol at a temperature of from about 55°C to about 70°C to form a solid; and

(ii)" filtering the solid to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $232^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

20. (currently amended): A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 9 comprising:

(a)' dissolving desloratadine in ethanol to form an ethanolic solution of desloratidine;

(b)' dissolving fumaric acid in ethanol to form an ethanolic solution of fumaric acid;

(c)' mixing the ethanolic solution of desloratidine and the ethanolic solution of fumaric acid at a temperature of from about 55°C to about 70°C to form a solid; and

(d)' filtering the solid to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $232^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

21. (previously presented): The process according to Claim 20 wherein the mixing in Step (c)' is conducted for a period of time from about 30 to about 45 minutes.

Remarks/Arguments

The Examiner has rejected Claims 7, 10, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villani (4,659,716) in view of Hansen (5,658,899) and/or Strupczewski (4,954,503) and/or Congy (5,290,951).

In response, applicants have cancelled Claims 7, 10, and 13.

The Examiner stated that Claims 8, 9, 11, 12, 14, 15 are allowed for reasons of record, and process Claims 16-21, if amended to depend on the allowable claims 8, 9 would also be allowable.

In response, applicants have amended Claims 16 and 17 to depend on Claim 8, and Claims 19 and 20 to depend on Claim 9.

Applicants have submitted herewith a supplemental information disclosure statement listing a reference which was cited in the International Search Report dated November 28, 2003. The reference is WO 02/42290, a copy of which is included herewith.

WO 02/42290 states on page 2, lines 1-5, of the PCT published application that Hungarian Patent No. 194 864 (U.S. 4,659,716, Villani) states that salts can be formed from desloratadine with pharmaceutically acceptable acids: hydrochloric acid, methanesulfonic acid, sulfuric acid, acetic acid, maleic acid, fumaric acid, and phosphoric acid. WO 02/42290 describes the following desloratidine salts: desloratidine disulfate, desloratidine dihydrogen chloride, desloratidine dihydrogen bromide, and desloratidine hemisulfate. It is noted that in Example 5 of WO 02/42290, a salt of desloratidine is prepared using maleic or fumaric acid, depending on ones' interpretation of the structure provided. As stated in the table on page 8, this desloratidine salt has a melting point of 169-171°C.

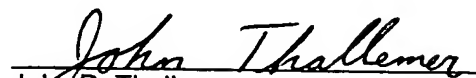
In contrast, applicants' polymorphic Forms 1 and 2 of desloratadine hemifumarate have a melting point, as determined by differential scanning calorimetry (DSC) of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $232^{\circ}\text{C} \pm 2^{\circ}\text{C}$, respectively, as claimed in applicants' Claims 16 and 19. Thus, the melting points of applicants' polymorphic Forms 1 and 2 of desloratadine hemifumarate are significantly different than the melting point of the desloratadine salt prepared according to WO 02/42290.

In addition, neither Villani, as noted by the Examiner, nor WO 02/42290 specifically describe polymorphic desloratadine hemifumarate, as claimed by applicants. Applicants' Claims 8 and 9 describe polymorphic Forms 1 and 2 of desloratadine hemifumarate by their respective powder X-ray diffraction patterns. Thus, WO 02/42290 does not teach or suggest applicants' polymorphic desloratadine hemifumarate, as claimed.

It is requested that the Examiner enter the above amendments, and pass the case to issue.

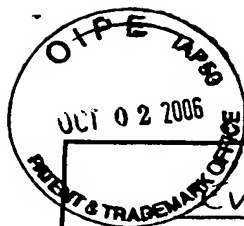
Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7945


John D. Thallemer
Attorney for Applicants
Reg. No. 34,940

Date: December 6, 2004

OCT 11 2005



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1625

RAY ET AL.

Examiner: Evelyn Huang

APPLICATION NO: 10/621,670

FILED: JULY 17, 2003

FOR: NOVEL SALT AND POLYMORPHS OF DESLORATADINE
HEMIFUMARATE

MS: Amendment

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

AMENDMENT

Sir:

The following amendment is in response to an Office Action dated March 7, 2005.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

10/31/11 2005

Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

Claims 1-7 (canceled).

8. (previously presented): A polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having by the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I₀"):

D	I/I₀
12.32	26
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10. (canceled).

11. (previously presented): A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 1 according to Claim 8 and a pharmaceutically acceptable carrier.

12. (previously presented): A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 according to Claim 9 and a pharmaceutically acceptable carrier.

13-15. (canceled).

OCT 11 2006

16. (previously presented): A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 8 comprising:

(i) mixing desloratadine, fumaric acid, and ethanol at a temperature of from about 15°C to about 25°C to form a solid; and

(ii) filtering the solid to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

17. (previously presented): A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 8 comprising:

(a) dissolving desloratadine in ethanol to form an ethanolic solution of desloratidine;

(b) dissolving fumaric acid in ethanol to form an ethanolic solution of fumaric acid;

(c) mixing the ethanolic solution of desloratidine and the ethanolic solution of fumaric acid at a temperature of from about 15°C to about 25°C to form a solid; and

(d) filtering the solid to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $224^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

18. (previously presented): The process according to Claim 17 wherein the mixing in Step (c) is conducted for a period of time from about 30 to about 45 minutes.

19. (previously presented): A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 9 comprising:

(i)' mixing desloratadine, fumaric acid, and ethanol at a temperature of from about 55°C to about 70°C to form a solid; and

(ii)" filtering the solid to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of $232^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

20. (previously presented): A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 9 comprising:

(a)' dissolving desloratadine in ethanol to form an ethanolic solution of desloratidine;

(b)' dissolving fumaric acid in ethanol to form an ethanolic solution of fumaric acid;

(c)' mixing the ethanolic solution of desloratidine and the ethanolic solution of fumaric acid at a temperature of from about 55°C to about 70°C to form a solid; and

(d)' filtering the solid to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C \pm 2°C.

21. (previously presented): The process according to Claim 20 wherein the mixing in Step (c)' is conducted for a period of time from about 30 to about 45 minutes.

Remarks/Arguments

By the present amendment, applicants have cancelled Claims 14 and 15. Therefore the claims remaining for consideration by the Examiner are Claims 8, 9, 11, 12, and 16-21. According to the Examiner, Claims 8, 9, 11, 12, and 16-21 are allowed.


The Examiner has rejected Claims 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over Villani (4,659,716) in view of Hansen (5,658,899) and/or Strupczewski (4,954,503) and/or Congy (5,290,951).

In response, applicants have cancelled Claims 14 and 15.

It is requested that the Examiner enter the above amendment, and pass the case to issue.

Respectfully submitted,

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Attorney for Applicants
Reg. No. 34,940

Date: March 28, 2005

OCT 11 2005



Notice of Allowability

Application No.

10/621,670

Examiner

Evelyn Huang

Applicant(s)

RAY ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3-28-2005.
2. ☒ The allowed claim(s) is/are 8,9,11,12,16,17,19 and 20.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

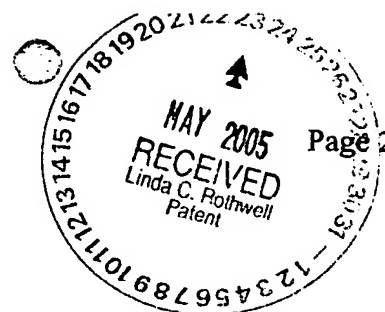
1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Evelyn Huang
Primary Examiner
Art Unit: 1625

5/20/05

Application/Control Number: 10/621,670

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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

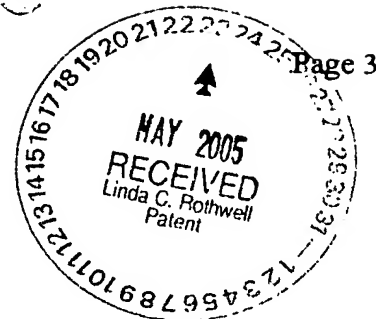
Authorization for this examiner's amendment was given in a telephone interview with Mr. Thallemer on 5-16-2005. During the interview, the examiner suggested amending claims 16-21 to be consistent with the description in the specification.

- a. Claim 16,
 - (i) replace 'mixing desloratadine, fumaric acid, and ethanol' with – mixing an ethanolic solution of desloratadine and fumaric acid --.
 - (i), before 'to form a solid', insert – and stirring for 30-45 minutes at this temperature--.
 - (ii), after 'filtering the solid', insert – at this temperature --.
- b. Claim 17,
 - (a), before 'ethanol', insert – anhydrous --.
 - (b), after 'ethanol', insert – anhydrous --.
 - (c), before 'to form a solid', insert – and stirring for 30-45 minutes at this temperature--.
 - (d), after 'filtering the solid', insert – at this temperature --.
- c. Cancel claim 18.
- d. Claim 19,
 - (i) replace 'mixing desloratadine, fumaric acid, and ethanol' with – mixing an ethanolic solution of desloratadine and fumaric acid --.
 - (i), before 'to form a solid', insert – and stirring for 30-45 minutes after mixing--.
 - (ii), after 'filtering the solid', insert – at this temperature --.

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e. Claim 20,

- (a), before 'ethanol', insert – anhydrous --.
- (b), after 'ethanol', insert – anhydrous --.
- (c), before 'to form a solid', insert – and stirring for 30-45 minutes after mixing--.
- (d), after 'filtering the solid', insert – at this temperature --.

f. Cancel claim 21.

g. In the specification, page 1, after the title, line 1, insert – This application claims the benefit of 60/401,153, filed on 8-5-2002 --.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

Claims 8, 9, 11, 12, 16, 17, 19, 20 are allowed.

The cancellation of claims 14, 15 has rendered moot the rejection under 35 U.S.C. 103(a) as being unpatentable over Villani (4659716, PTO-1449) in view of Hansen (5658899) and/or Strupczewski (4954503) and/or Congy (5290951).

Villani (4659716, PTO-1449) discloses descarbonylethoxyloratadine and the pharmaceutically acceptable salts (including the fumarate and the hydrates thereof, column 26, claim 3; column 1). Lacking is the teaching or suggestion to prepare the instant polymorph form 1 or 2 of descarbonylethoxyloratadine hemifumarate having the characteristic X-ray diffraction pattern.

WO 99/01450 (PTO-1449) or Schumacher (6506767, the US equivalent of WO 99/01450) discloses polymorphs of descarbonylethoxyloratadine. The instant is a polymorph form of descarbonylethoxy-loratadine hemifumarate having X-ray diffraction patterns different from Schumacher's polymorphs. Absent is the teaching or suggestion to prepare the instant polymorph form 1 or 2 of descarbonylethoxy-loratadine hemifumarate having the characteristic X-ray diffraction pattern.

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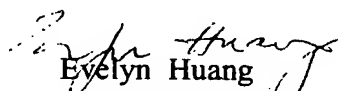
Furthermore, the instant polymorphs 1 and 2 has high water solubility, and the stability study indicates that the instant polymorphs 1 and 2 are more stable than free base desloratadine under stressed condition. Both polymorphs do not change the polymorphic form even after crushing into a solid powder form (pages 3-4 of the specification).

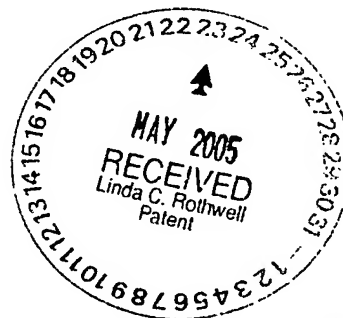
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625



OCT 11 2006